NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SCHERING CORPORATION, et al., Plaintiffs, v. MYLAN PHARMACEUTICALS, INC., et al., Defendants.	Civil Action No.: 09-6383 (JLL) **OPINION**

LINARES, District Judge.

This matter comes before the Court by way of a motion for partial summary judgment filed by Plaintiffs, Schering Corporation and MSP Singapore Company LLC (collectively, "Schering"), on July 8, 2011, seeking summary judgment on certain of Defendant Mylan Pharmaceuticals, Inc.'s ("Mylan's") inequitable conduct defenses and counterclaims, and a motion for partial summary judgment also filed by Schering on July 8 seeking summary judgment on the issue of infringement and on Mylan's invalidity defenses of indefiniteness, inherent anticipation, and lack of enablement. The Court has considered the submissions of the parties in support of and in opposition to the present motions and decides the matter without oral argument pursuant to Rule 78 of the Federal Rules of Civil Procedure. For the reasons set forth below, Schering's motions are granted in part and denied in part.

I. BACKGROUND

On December 16, 2009, Schering filed a Complaint alleging that Mylan's filing of an

Abbreviated New Drug Application (ANDA) infringed two of Schering's patents, specifically United States Patent Nos. RE37,721 ("the '721 patent") and 5,846,966 ("the '966 patent"). (Schering's Local Civ. R. 56.1 Stmt. of Uncontested Facts in Support of Their Mot. for Summ. J. on Mylan's Inequitable Conduct Defenses and Counterclaims ["SOF"] ¶ 9.) The '721 patent discloses the hydroxy-substituted azetidinone compound ezetimibe, which is marketed and sold commercially as the drug Zetia. In non-scientific terms, Zetia is used to reduce cholesterol levels by blocking the absorption of cholesterol from a person's diet. The '966 patent discloses the combination of ezetimibe with an HMG CoA reductase inhibitor, another type of drug that is designed to reduce cholesterol levels. This combination is marketed and sold commercially as the drug Vytorin.

On June 14, 2011, the '721 patent reissued as the United States Patent No. RE42,461 ("the '461 patent"). (SOF ¶ 6.) On June 15, 2011, this Court issued a Markman Opinion and Order construing certain terms in claims 8, 9, 12, and 13 of the '721 patent and in claims 1 and 3 of the '966 patent. (Docket Entry Nos. 209 ["Markman Op."], 210.) Thereafter, Schering sought and was granted, without opposition, leave to amend its Complaint, and on July 25, 2011, an Amended Complaint was filed alleging infringement of the '461 and '966 patents. (Docket Entry No. 254.) On July 8, 2011, Schering filed the instant motions for partial summary judgment.[1]

II. LEGAL STANDARD

A court shall grant summary judgment under Rule 56(c) of the Federal Rules of Civil

[1]Mylan has been granted an extension of time to file an Answer to Schering's Amended Complaint. Mylan's briefing in connection with the instant motions does not indicate that Mylan's presumably forthcoming Second Amended Answer will alter the defenses and counterclaims at issue here, except to the extent that Mylan states that it intends to withdraw certain of those defenses and counterclaims.

Procedure "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).

On a summary judgment motion, the moving party must show, first, that no genuine issue of material fact exists. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). The burden then shifts to the non-moving party to present evidence that a genuine issue of material fact compels a trial. Id. at 324. In so presenting, the non-moving party must offer specific facts that establish a genuine issue of material fact, not just "some metaphysical doubt as to the material facts." Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 586–87 (1986). Thus, the non-moving party may not rest upon the mere allegations or denials in its pleadings. See Celotex, 477 U.S. at 324. Further, the non-moving party cannot rely on unsupported assertions, bare allegations, or speculation to defeat summary judgment. See Ridgewood Bd. of Educ. v. N.E. ex rel. M.E., 172 F.3d 238, 252 (3d Cir. 1999). The Court must, however, consider all facts and their reasonable inferences in the light most favorable to the non-moving party. See Pennsylvania Coal Ass'n v. Babbitt, 63 F.3d 231, 236 (3d Cir. 1995).

III. DISCUSSION

Mylan has stated that it withdraws both its inherent anticipation defense and its claim of inequitable conduct for Schering's alleged false statements during the prosecution of the '461 patent regarding "preventing" atherosclerosis. (Mylan's Br. In Opp'n to Pl.'s Mot. for Partial Summ. J. of Infringement and No Invalidity with Respect to Certain Mylan Defenses and Countercl. ["Mylan's Certain Defenses Opp'n Br."] at 5–6, 10–11; Mylan's Br. in Opp'n to Pl.'s Mot. for Partial Summ. J. as to Certain of Mylan's Inequitable Conduct Defenses and Countercl.

["Mylan's Inequitable Conduct Opp'n Br."] at 6.) As such, Schering's motions for summary judgment on Mylan's inherent anticipation defense and its claim of inequitable conduct for the alleged false statements will be denied without prejudice pending Mylan's filing of a Second Amended Answer.[2] Mylan likewise does not oppose Schering's motion for summary judgment on (A) the issue of infringement, but Mylan does oppose Schering's motions for summary judgment on its defenses and counterclaims of (B) inequitable conduct for failure to disclose certain metabolite information to the United States Patent and Trademark Office (PTO) in connection with Schering's prosecution of the '721 and '966 patents, (C) indefiniteness of certain claims in the '461 and '966 patents, and (D) lack of enablement of certain claims in the '461 patent. The Court addresses these issues in turn.

A. Infringement

Schering's Amended Complaint alleges that Mylan's proposed ANDA products infringe claims 3 and 10–13 of the '461 patent and "one or more" claims of the '966 patent. (Am. Compl. ¶ 39.) Schering now moves for summary judgment that those products literally infringe claims 3 and 10–13 of the '461 patent and claims 2–4 of the '966 patent. (Schering's Br. in Supp. of Their Mot. for Partial Summ. J. of Inf. and No Invalidity with Respect to Certain Mylan Defenses and Countercl. ["Schering's Certain Defenses Opening Br."] at 8.) Mylan's August 1, 2011 brief in opposition to Schering's motion indicated that Mylan planned to enter a joint stipulation on the issue of infringement and asked the Court to defer ruling on the matter pending such stipulation. (Mylan's Certain Defenses Opp'n Br. at 6.) However, by way of a letter dated

[2]Mylan may also, of course, withdraw these defenses and counterclaims by way of any other appropriate filing.

August 17, 2011, Mylan informed the Court that the parties have been unable to reach an agreement, stating that "the issue remains ripe for the Court's adjudication based on the facts in the record." (Docket Entry No. 287.) As such, the Court will consider the merits of Schering's motion.

"Literal infringement exists if each of the limitations of the asserted claim(s) read on, that is, are found in, the accused device." Tate Access Floors, Inc. v. Interface Architectural Res., Inc., 279 F.3d 1357, 1366 (Fed. Cir. 2002). A determination of infringement is composed of two steps. Oakley, Inc. v. Sunglass Hut Intern., 316 F.3d 1331, 1339 (Fed. Cir. 2003). First, the court construes the scope and meaning of the asserted claims. Id. (citing Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc) (citations omitted)). Next, the court compares the construed claims to the allegedly infringing device and determines for each claim whether every limitation of that claim is found in the accused device. Oakley, 316 F.3d at 1339 (citing Warner-Jenkinson Co. v. Hilton-Davis Chem. Co., 520 U.S. 17, 29 (1997)). While the initial determination is a matter of law, the second is a question of fact. Zelinski v. Brunswick Corp., 185 F.3d 1311, 1315 (Fed. Cir. 1999) (citing Cybor, 138 F.3d at 1451, 1456; North Am. Vaccine, Inc. v. Am. Cyanamid Co., 7 F.3d 1571, 1574 (Fed. Cir. 1993)).

By way of its June 15, 2011 Markman Opinion and Order, the Court conducted the first step of the infringement analysis by construing the disputed claims of the '721 and '966 patents. The '721 patent has since reissued as the '461 patent, and the parties do not dispute that claims 3 and 10–13 of the '721 patent are substantially identical to claims 3 and 10–13 of the '461 patent. (Mylan's Resp. to Pls.' Local Civil Rule 56.1 Stmt. ¶ 17.) The parties likewise do not dispute that the portions of the Court's Markman Order construing claim terms in the '761 patent have

equal application to the corresponding terms of the '461 patent. (Id. at ¶¶ 15–17.) With respect to the second step of the infringement analysis, Mylan admits that its proposed ANDA products "comprise ezetimibe and the inactive form of simvastatin—which under the Court's claim construction are compounds claimed in the '461 and '966 patents." (Mylan's Certain Defenses Opp'n Br. at 3 (citation omitted); see Mylan's Resp. to Pls.' Local Civil Rule 56.1 Stmt. at ¶¶ 20, 22.) Furthermore, Mylan's August 17, 2011 letter to the Court confirms that in its opposition papers Mylan "could not dispute that, under the Court's claim construction, Mylan's proposed ANDA products would infringe claims 3 and 10–12 of the '461 patent and claims 2–4 of the '966 patent." Indeed, Mylan's briefs have raised no such dispute. There is thus no genuine issue of material fact that all elements of claims 3 and 10–12 of the '461 patent and all elements of claims 2–4 of the '966 patent are found in Mylan's proposed ANDA products. As such, Schering's motion for summary judgment on the issue of infringement is granted.

B. Inequitable Conduct for Failure to Disclose Metabolite Information

Schering argues that under the new standard of inequitable conduct announced in Therasense, Inc. v. Becton, Dickinson and Co., --- F.3d ----, 2011 WL 2028255 (Fed. Cir. 2011) (en banc), it is entitled to summary judgment on Mylan's claim that it committed inequitable conduct by allegedly failing to disclose to the PTO that several of the compounds claimed in the '721 and '966 patents were metabolites of a prior art compound, SCH48461. In Therasense, the Federal Circuit revised the law of inequitable conduct by "tighten[ing] the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public." 2011 WL 2028255, at *9. With respect to the intent prong, the accused infringer must now "prove that the patentee acted with the specific intent to deceive the PTO." Id. The

court explained:

> In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference. In other words, the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.

Id. (citations and quotations omitted).

The court then went on to adopt a "but for" standard of materiality. Under this standard, "[w]hen an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art." Id. at *11. "In making this patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction." Id. (citing Manual of Patent Examining Procedure §§ 706, 2111 (8th ed. Rev.8, July 2010)).[3] Finally, if the accused infringer "prove[s] both elements—intent and materiality—by clear and convincing evidence,"[4] the court must still "weigh the equities to determine whether the applicant's conduct before the PTO warrants rendering the entire patent unenforceable." Id. at *6.

Schering first contends that under Therasense's heightened materiality standard, Mylan cannot show that the patents would not have issued "but for" Schering's failure to disclose the metabolite information, because at the time the patents were prosecuted—from in or about March 1996 through May 2002—the examiner did not have the benefit of Federal Circuit's decision in

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[3]The court, however, also recognized an exception to the "but for" standard in cases of "affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit." Id. at *12.

[4]The Geneva opinion does not explain the interaction between the "clear and convincing" standard referenced here and the preponderance standard adopted with the respect to the patentability determination to be made under the materiality prong.

Schering Corporation v. Geneva Pharmaceuticals, 339 F.3d 1373 (Fed. Cir. 2003). Schering describes the Geneva decision as a "seismic shift" in law of inherent anticipation, creating a requirement to disclose metabolite information that had not previously existed. (Schering's Inequitable Conduct Br. at 13.) Mylan responds that Geneva was not the upheaval that Schering imagines, instead arguing that the decision was a "logical extension" of the law of inherent anticipation based on then-existing precedent. (Mylan's Inequitable Conduct Opp'n Br. at 11.) Mylan thus contends that even under the law of inherent anticipation pre-Geneva, a failure to disclose that a claimed compound formed as metabolite from a prior art compound could constitute inequitable conduct.

In Geneva, the Federal Circuit squarely addressed whether a compound that formed as a metabolite of a known compound, when used as taught in the prior art, was inherently anticipated by that prior art compound. 339 F.3d at 1376. Noting that the matter before it "may be a case of first impression," the Federal Circuit observed that under existing precedent, "[a] patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention," id. at 1377 (citing Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987), and "a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference," id. (citing Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991)). Then, reasoning that an inherent disclosure of a metabolite by way of the express disclosure of its metabolic precursor placed "subject matter in the public domain as well as an express disclosure" of the metabolite, the court concluded that "the inherent disclosure of the entire claimed subject matter anticipates as well as inherent disclosure of a single feature of

the claimed subject matter." Id. at 1379. Thus, Geneva did not expressly overrule any of the Federal Circuit's previous decisions, and the court itself stated that the case may have been one of first impression, suggesting that no definitive statement had yet been made on the subject. This Court therefore agrees with Mylan that Geneva was not so great a shift in the patent law as to require the Court to find that an accused infringer could not make a "but for" showing of materiality with respect to a nondisclosure that occurred prior to that 2003 decision. While, as Schering notes, the PTO had previously issued patents on metabolites of known compounds, this Court is not convinced that the law of inherent anticipation pre-Geneva was as settled with respect to the patentability of such compounds as Schering contends. While patents are entitled to a presumption of validity, Schering has pointed to no case in which similar metabolite claims were affirmatively found valid, and Mylan need only prove by a preponderance of the evidence that the PTO would have denied Schering's claims had it been aware of the undisclosed reference. Therasense, 2011 WL 2028255, at *11. The Court therefore concludes that summary judgment based solely on the timing of the Geneva decision would be inappropriate.

Schering alternatively contends that Mylan has failed to put forth sufficient evidence to show that Schering acted with specific intent to deceive the PTO, as required under the heightened scienter requirement announced in Therasense. While Schering does not appear to dispute that it had knowledge of the metabolite information during prosecution,[5] Schering does

[5]Schering instead disputes whether, under Geneva, "the purported metabolites necessarily and inevitably formed in all mammals." (Pls.' Reply Br. in Supp. of Their Mot. for Partial Summ. J. on Mylan's Inequitable Conduct Defenses and Countercl. ["Schering's Inequitable Conduct Reply Br."] at 7 n.2.) This is a separate inquiry from whether Schering knew during prosecution that the claimed compounds were, in a general sense, metabolites of the prior art compound. Furthermore, at a minimum, any dispute on this issue presents a triable issue of fact, as Mylan refers to multiple drug report summaries allegedly in the possession of the inventors

contend that Mylan has failed to put forth evidence both that Schering knew that such information would be material to the PTO's decision and that Schering deliberately withheld that information from the agency. Schering specifically argues that no evidence has been presented to counter the statements of Schering's in-house counsel, Anita Magatti, that at the time the patents were prosecuted she believed that metabolites of prior art compounds were patentable. (Schering's Inequitable Conduct Reply Br. at 7.) Mylan, however, responds to these assertions by pointing to the very same evidence. Mylan notes that when Ms. Magatti was asked to provide the basis her belief, she stated that she could not recall. (Mylan's Inequitable Conduct Opp'n Br. at 12 (citing Mukerjee Decl., Ex. 14 at 183:6–23).) Indeed, Ms. Magatti stated that she could not remember if she had ever read the Geneva opinion. (Id. (citing Mukerjee Decl., Ex. 14 at 184:4–24).) Mylan finally cites the pre-Geneva case law of inherent anticipation, noting that both it and the 1995 version of the PTO's Manual of Patent Examining Procedure generally stated that a feature inherent in the prior art was not patentable even if it was previously unrecognized. (Id. at 11.) The Court thus finds that the testimony of Ms. Magatti does not conclusively resolve the question of intent.

Given that "direct evidence of deceptive intent is rare," Therasense, 2011 WL 2028255, at *10, and drawing all reasonable inferences in the light most favorable to Mylan, the non-moving party, the Court concludes that Mylan has put forth sufficient indirect and circumstantial evidence from which a reasonable fact finder could conclude that Schering had knowledge of the materiality of the withheld prior art. As this showing appears to depend at least in part on the

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that, Mylan states, identified the compounds as metabolites of SCH48461. (See Mylan's Inequitable Conduct Opp'n Br. at 7–8.)

testimony of Ms. Magatti and the question of her credibility, a genuine issue of material fact exists as to this element of the inequitable conduct inquiry. Furthermore, given that Schering does not appear to dispute that it had knowledge of the relevant prior art, a deliberate decision to withhold that information could likewise be reasonably inferred from the evidence already presented. This Court thus concludes that genuine issues of material fact preclude summary judgment on this inequitable conduct claim.

C. Indefiniteness

Mylan contends that claims 8, 9, 12, and 13 of the '461 patent and claims 1 through 10 of the '966 patent are invalid under 35 U.S.C. § 112, ¶ 2, because the terms "treatment," "treating," "preventing," "prevention," and "an effective amount" are indefinite. In its motion for partial summary judgment, Schering argues that because the Court's Markman Opinion construed each of these allegedly indefinite claim terms, their corresponding claims are amenable to construction and are therefore definite. Mylan responds that the issue of definiteness depends on underlying factual issues as to the understanding of the skilled artisan, making summary judgment inappropriate.

Contrary to Mylan's assertions, however, the Federal Circuit has routinely held that the "determination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." Exxon Research and Eng'g Co. v. United States, 265 F.3d 1371, 1376 (Fed. Cir. 2001) (quoting Personalized Media Commc'ns, LLC v. Int'l Trade Com'n, 161 F.3d 696, 705 (Fed. Cir. 1998); see Wellman, Inc. v. Eastman Chemical Co., 642 F.3d 1355, 1365 (Fed. Cir. 2011) ("The review of indefiniteness under 35 U.S.C. § 112, paragraph 2, proceeds as a question of law without deference."); Microprocessor

Enhancement Corp. v. Texas Instruments Inc., 520 F.3d 1367, 1374 (Fed. Cir. 2008) ("Whether a claim reasonably apprises those skilled in the art of its scope is a question of law that we review de novo.") (citing Exxon Research). While "a court may consider or reject certain extrinsic evidence in resolving disputes en route to pronouncing the meaning of claim language, 'the court is not crediting certain evidence over other evidence or making factual evidentiary findings. Rather, the court is looking to the extrinsic evidence to assist in its construction of the written document.' " Exxon Research, 265 F.3d at 1376 (quoting Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998)); but see Green Edge Enterprises, LLC v. Rubber Mulch Etc., LLC, 620 F.3d 1287, 1299 (Fed. Cir. 2010) (observing generally that definiteness is a question of law with "underlying factual determinations," but without undertaking a definiteness analysis).

In contending that genuine issues of material fact exist here, Mylan points to the declaration of its expert, Dr. Stanley J. Schneller,[6] who has opined that the specifications do not teach the person of ordinary skill what quantities of the claimed compound must be administered in order to deliver "an effective amount" to treat or prevent atherosclerosis, as recited in various claims of the '461 and '966 patents. (Mylan's Certain Defenses Opp'n Br. at 9.) Mylan thus argues that factual questions regarding the understanding of the skilled artisan remain at issue. However, in the context of claim definiteness, the understanding of a person of ordinary skill in the relevant art and the content and interpretation of the intrinsic and extrinsic evidence are

[6]Dr. Schneller's declaration was originally filed neither as a sworn affidavit nor as an unsworn declaration made under penalty of perjury pursuant to 28 U.S.C. § 1746; see Pagan v. Holder, 741 F. Supp. 2d 687, 694 n.11 (D.N.J. 2010) (holding that such statements "cannot be considered on a motion for summary judgment"). However, on August 16, 2011, Mylan submitted two corrected copies of the Schneller declaration—one for each of Schering's motions—conforming to the requirements of § 1746. (See Docket Entry Nos. 283, 284.) The Court here refers to the corrected copy. (See Docket Entry No. 284.)

"underlying" factual matters to be considered by the Court as the construer of patent claims, not evidentiary issues requiring resolution by a fact finder. See Exxon Research, 265 F.3d at 1376. As such, Mylan's disputes regarding the understanding of a person of ordinary skill in the art do not constitute genuine issues of material fact with respect to the issue of definiteness, and the matter may therefore be resolved at summary judgment.

To establish that a claim in indefinite, an accused infringer must show "by clear and convincing evidence that a skilled artisan could not discern the boundaries of the claim based on the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant art area." Halliburton, 514 F.3d at 1249–50. The Court thus looks to determine whether the claim is "not amenable to construction or [is] insolubly ambiguous." Datamize LLC v. Plumtree Software, Inc., 417 F.3d 1342, 1347 (Fed. Cir. 2005). Here, Schering argues that because the Court properly construed the terms "treatment," "treating," "preventing," "prevention," and "an effective amount" in its Markman Opinion, the claims associated with those terms are "amenable to construction" and are thus definite as a matter of law. As Mylan correctly notes, however, a Court's construction of a claim term during Markman proceedings does not necessarily defeat an accused infringer's definiteness argument with respect to the entire claim. See, e.g., Power-One, Inc. v. Artesyn Techs., Inc., 599 F.3d 1343, 1348–51 (Fed. Cir. 2010) (affirming the district court's construction of the term "POL regulator" while separately affirming its holding that the claim was not indefinite); Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1371 (Fed. Cir. 2008) ("The parties do not dispute the claim constructions reached by the district court, and the district court did construe all terms relevant to this appeal. In and of itself, a reduction of the meaning of a claim term into words is not

dispositive of whether the term is definite.") (citing Halliburton Energy Serv., Inc. v. M-I LLC, 514 F.3d 1244, 1251 (Fed. Cir. 2008)). Nonetheless, this Court finds that based on the intrinsic and extrinsic evidence, claims 8, 9, 12, and 13 of the '461 patent and claims 1 through 10 of the '966 patent are not indefinite.

The Court first examines the relevant claims of the '461 patent. Claims 8 reads, "A pharmaceutical composition for the treatment or prevention of atherosclerosis, or for the reduction of plasma cholesterol levels, comprising an effective amount of a compound of claim 7 in a pharmaceutically acceptable carrier." Claim 7, the independent claim from which claim 8 depends, is directed to a class of hydroxy-substituted azetidinone hypocholesterolemic agents, and its definiteness is not in dispute. Claim 12 is nearly identical to claim 8, except that it depends from claims 10 and 11, and the definiteness of those claims is likewise undisputed. Claim 9 of the '461 patent reads, "A method of treating or preventing atherosclerosis or reducing plasma cholesterol levels comprising administering to a mammal in need of such treatment an effective amount of a compound of claim 7." Claim 13 is identical to claim 9, except that, like claim 12, it depends from claims 10 and 11. As Schering notes, the Court has already found the terms "treatment," "treating," and "an effective amount," as used in these claims, to be amendable to construction. See Markman Op. at 29.[7] Furthermore, the parties previously agreed to constructions of the terms "preventing" and "prevention." Id. at 8. Reading the allegedly indefinite claims as a whole in light of these constructions, and in consideration of the intrinsic and extrinsic evidence, the Court finds that Mylan has failed to show clearly and convincingly

[7]The Court also construed the terms "reduction of plasma cholesterol levels," "reducing plasma cholesterol levels," and "pharmaceutically acceptable carrier," Markman Op. at 29, and the parties agreed to a construction of the term "atherosclerosis," id. at 9 n.8.

that a person of ordinary skill in the art could not discern the boundaries of these claims. Nearly all of the relevant claim terms have already been construed, and the intrinsic evidence demonstrates how the claimed compounds may be administered to treat or prevent atherosclerosis. The specification describes, for example, the formation of oral doses in specified amounts and the role that inhibiting the absorption of dietary cholesterol may play in stopping, slowing, or reversing the progression of this disease. See U.S. Patent No. RE42,461 col. 19:66–20:54 (describing the biological effects of the drug and giving estimated doses based on body weight). While the degree to which a drug is "effective" may depend on the "treatment" or "prevention" outcome sought, the skilled artisan reading these claims would certainly understand, based on the example amounts given in the specification, the biological mechanisms at work, and nature of the disease being treated or prevented, the basic parameters that define "an effective amount" of the claimed compounds.[8] As such, this Court finds that claims 8, 9, 12, and 13 of the '461 patent are not indefinite.

As to claims 1 through 10 of the '966 patent, Mylan focuses its indefiniteness argument on the meaning of the term "an effective amount." (See Mylan's Certain Defenses Opp'n Br., Declaration of Deepro R. Mukerjee ["Mukerjee Decl."], Ex. 7 at 130–32.) Claims 1 and 6 of the '966 patent use the term "an effective amount," while the other claims of the patent employ that term only by incorporation, as dependent claims. Claim 1 reads, "A pharmaceutical composition for the treatment or prevention of atherosclerosis, or for the reduction of plasma cholesterol

[8]This does not mean, however, that the claims are sufficiently enabled. The Court here only considers whether the limits of the claims are discernible, not whether the specification provides adequate guidance to enable a person of ordinary skill to practice those claims without undue experimentation.

levels, comprising an effective amount of a compound represented by the formula I . . . or a pharmaceutically acceptable salt thereof . . . in combination with an HMG CoA reductase inhibitor in a pharmaceutically acceptable carrier."[9] Claim 6 reads, "A method of treating or preventing atherosclerosis or reducing plasma cholesterol levels comprising administering to a mammal in need thereof an effective amount of a compound represented by the formula I . . . or a pharmaceutically acceptable salt thereof . . . in combination with an effective amount of a cholesterol biosynthesis inhibitor selected from the group consisting of HMG CoA reductase inhibitors."[10] Claim 1 is thus a compound claim, claim 6 is method claim, and both claims are directed toward treating or preventing atherosclerosis—or reducing cholesterol levels—by way of "effective" amounts of the claimed compounds.

For the reasons already stated with respect to the disputed claims of the '461 patent, this Court finds that claims 1 and 6 of the '966 patent are not invalid for indefiniteness. The '966 patent shares a specification with the '461 patent, so the Court's intrinsic evidence findings apply with equal force to the '966 patent. Indeed, claims 1 and 6 of the '966 are essentially identical to the claims of the '461 patent that this Court has already analyzed, with the only significant difference being that the '966 patent is directed to the combination of ezetimibe with HMG CoA

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[9]For clarity, the Court omits various chemical compound representations given in the claim, which are not at issue here. Also, with respect to this claim, the Court's Markman Opinion additionally construed "treatment," "reduction of plasma cholesterol levels," "HMG CoA reductase inhibitor," and "pharmaceutically acceptable carrier," and the parties agreed to constructions of "prevention" and "atherosclerosis."

[10]The Court again omits the chemical compound representations. With respect to this claim, the Court's Markman Opinion also construed "treating," "reducing plasma cholesterol levels," and "administering," and the parties agreed to constructions of "preventing" and "atherosclerosis."

reductase inhibitors. While this Court has construed the dosage forms of the '461 and '966 patents differently, see Markman Op. at 15, 19 (finding an ingestion limitation with respect to the '721 patent but not the '966 patent), this distinction has no bearing on a skilled artisan's understanding of the amounts to which those doses refer. The limits of the meaning of "an effective amount" as used in these claims can thus be readily discerned from the claim language and specification, and Mylan has failed to demonstrate that the claim language or intrinsic evidence require any conclusion to the contrary. Finally, because claims 2–5 and 7–9 of the '966 patent depend from claims 1 and 6 and do not otherwise contain the disputed "effective amount" language, this Court finds that those claims are likewise definite. As such, Schering's motion for summary judgment on Mylan's defense of indefiniteness is granted.

D. Lack of Enablement

Like its arguments with respect to indefiniteness, Schering contends that in light of the claim constructions adopted in this Court's Markman Opinion it is entitled to summary judgment on Mylan's defense that claims 8, 9, 12, and 13 of the '461 patent are invalid for lack of enablement of the term "an effective amount." (See Mukerjee Decl., Ex. 7 at 107–122.) Schering argues that because the Court limited the term "an effective amount" to oral dosage forms, the claims are enabled by the language in the specification detailing "actual data showing a milligram-per-kilogram (mg/kg) dose of ezetimibe that resulted in a percentage reduction of cholesterol." (Schering's Certain Defenses Opening Br. at 8 (citing United States Patent No. RE42,461 col. 36:9–43 (table disclosing dose amounts and their associated responses)).) Mylan responds that genuine issues of material fact preclude summary judgment on this issue, noting that Schering's opening brief entirely failed to consider the canonical enablement factors set forth

in In re Wands, 858 F.2d 731 (Fed. Cir. 1988).

Enablement is a question of law based on underlying factual determinations. Falko-Gunter Falkner v. Inglis, 448 F.3d 1357, 1363 (Fed. Cir. 2006) (citing Wands, 858 F.2d at 737). To be enabling, "[t]he specification must 'enable one of ordinary skill in the art to practice the claimed invention without undue experimentation.' " Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc., 617 F.3d 1296, 1305 (Fed. Cir. 2010) (quoting Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999)). Factors to be considered in determining whether a disclosure would require undue experimentation include:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Wands, 858 F.2d at 737. The Wands factors entail factual inquiries that may preclude summary judgment. See Transocean, 617 F.3d at 1305–07 (finding genuine issues of material fact regarding the development necessary to enable a transfer mechanism for an offshore drilling apparatus in light of the state of the prior art).

Mylan argues that genuine issues of material fact exist as to whether undue experimentation would be required for a person of ordinary skill to make a formulation comprising "an effective amount" of ezetimibe based on the specification of the '461 patent. Mylan relies in part on the declaration of Dr. Schneller,[11] who opines that the specification

[11]As noted above, the Court refers to the Corrected Declaration of Dr. Stanley J. Schneller. (Docket Entry No. 284.)

provides no data with respect to the amounts of ezetimibe required to effectively treat or prevent atherosclerosis in humans, instead providing only "minimal hamster data on serum cholesterol levels." (Mylan's Certain Defenses Opp'n Br. at 15; see Docket Entry No. 284, Corrected Declaration of Dr. Stanley J. Schneller ¶ 15.) According to Mylan, the "actual data" provided in the specification regarding dose amounts give only "a starting point, at best, which would lead a person of skill into further research." (Id. at 14.) Schering responds that Schneller's statements are no more than "bare assertions and conclusory allegations." (Schering's Reply Br. in Supp. of Their Motion for Partial Summ. J. of Inf. and No Invalidity with Respect to Certain Mylan Claims and Defenses ["Schering's Certain Defenses Reply Br."] at 5.) Schering instead points to the testimony of Mylan's own expert, Dr. Morris Brown, wherein he described how a "dose response curve" demonstrates that a "range of doses" may "achieve a range of effects," thus providing a reliable method of determining dose amounts. (SOF ¶ 33.) Schering argues that, based on the Federal Circuit's decision in United States v. Telectronics, Inc., 857 F.2d 778 (Fed. Cir. 1988), a person of ordinary skill "would know how to conduct a dose response study," just as Dr. Morris describes. (Schering's Certain Defenses Reply Br. at 6.) Schering thus argues that even if the specification provides only "a starting point" for determining what constitutes an effective amount for a broader population, those amounts could readily be determined using techniques familiar to a person of ordinary skill in the art.

While Schering is correct that many of Dr. Schneller's statements regarding enablement are not especially detailed, the Court finds that his declarations are nonetheless supported by an adequate factual basis to raise a genuine issue of material fact. In addition to his comments on the hamster data, Dr. Schneller opines that the doses of ezetimibe described in the specification

are "exceedingly high" compared to the amounts known to be administered to humans in practice, and he further observes that the response data given listed specification show a wide variation in the effectiveness of other hydroxy-substituted azetidinones, thus suggesting a high level of unpredictability in the art. (Docket Entry No. 284, Corrected Declaration of Dr. Stanley J. Schneller ¶¶ 21–22.) Dr. Schneller also notes that the specification provides that effective dose amounts depend on factors including "the potency of the compound administered, the age, weight, condition and response of the patient," but he observes that the specification does not provide any guidance for a person of ordinary skill to determine the appropriate dose based on those factors. (Id. at ¶ 20 (quoting U.S. Patent No. RE37,721 col. 2:34–37).) Dr. Schneller thus offers more than conclusory allegations of lack of enablement and instead provides an analysis of the facts underlying the disclosure.

The Court further finds that Schering's reliance on Telectronics is misplaced. The enablement issue in that case was decided based on evidence presented at a trial on the merits, not at summary judgment, and this Court does not read Telectronics as holding that a skilled artisan's ability to conduct a dose response study automatically renders a specification enabling, particularly given that "the predictability or unpredictability" of such experimentation may vary with the art being considered. See 857 F.2d at 785 (disagreeing with multiple of the district court's conclusions while noting that the district court's finding that "those who were expert in the field [of bone growth stimulation] . . . would know how to conduct a dose response study" actually weighed against its holding of lack of enablement). This Court thus finds based on the evidence presented that genuine issues of material fact exist with respect to the Wands factors. Summary judgment on the issue of enablement is therefore inappropriate.

IV. CONCLUSION

For the foregoing reasons, Schering's motions for partial summary judgment are granted in part and denied in part. An appropriate Order accompanies this Opinion.

DATED: August 22, 2011

/s/ Jose L. Linares
JOSE L. LINARES
UNITED STATES DISTRICT JUDGE